

1 SNELL & WILMER L.L.P.
Don Bivens (#005134)
2 Nicole E. Sornsin (#027321)
One Arizona Center
3 400 East Van Buren
Phoenix, AZ 85004-2202
4 Telephone: (602) 382-6000
dbivens@swlaw.com
5 nsornsin@swlaw.com

6 CRAVATH, SWAINE & MOORE LLP
Daniel Slifkin (*pro hac vice*)
7 David M. Stuart (*pro hac vice*)
Worldwide Plaza
8 825 Eighth Avenue
New York, NY 10019
9 Telephone: (212) 474-1000
dslifkin@cravath.com
10 dstuart@cravath.com

11 Attorneys for Defendants

12 **UNITED STATES DISTRICT COURT**
13 **DISTRICT OF ARIZONA**
14

15 Richard Di Donato, Individually and
On Behalf of All Others Similarly
16 Situated,

17 Plaintiff,

18 v.

19 Insys Therapeutics, Inc.; Michael L.
Babich; Darryl S. Baker; and John N.
20 Kapoor,

21 Defendants.

No. 16-cv-302-NVW

**DEFENDANTS' MOTION TO
DISMISS CLASS ACTION
COMPLAINT**

**ORAL ARGUMENT
REQUESTED**

22
23
24
25
26
27
28

Defendants Insys Therapeutics, Inc. (“Insys” or the “Company”), Michael L. Babich, Darryl S. Baker and John N. Kapoor move to dismiss Plaintiff Richard Di Donato’s Class Action Complaint (“Complaint”) for failure to state a claim, pursuant to Rules 8, 9, and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u *et seq.* (“PSLRA”).¹

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiff’s Complaint recycles old allegations of misconduct from a prior securities fraud case against Insys, which settled in December 2015, into a supposedly new case of securities fraud. Allegations of misconduct that Plaintiff says Insys failed to disclose were well-publicized (including by Insys itself) before the members of the putative class in this case bought shares in the Company. None of the information disclosed during the Class Period was new news that revealed that the Defendants’ statements were false or misleading. Because Plaintiff’s Complaint does not sufficiently plead actionable misstatements, scienter or loss causation, it should be dismissed.

II. STATEMENT OF FACTS

On a motion to dismiss, courts may consider “the complaint, materials incorporated into the complaint by reference, and matters of which the court may take judicial notice”, including prior court filings and the Company’s publicly available financial documents. *See Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1061 & 1064 n.7 (9th Cir. 2008). Accordingly, solely for this motion, Defendants assume the well-pleaded allegations in the Complaint to be true, but refer also to court submissions and the Company’s Securities and Exchange Commission filings, both of which have been in the public domain. (*See Defendants’ Request for Judicial Notice in Support of the Motion to Dismiss the Complaint filed together with this Motion.*) The

¹ Pursuant to the Order entered by the Court on February 3, 2016, Defendants’ counsel certify that the parties conferred on March 9, 2016 to determine whether an amendment could cure the deficient Complaint and have been unable to agree that the Complaint is curable by permissible amendment.

1 chronology of relevant events is as follows.

2 **A. Pre-Complaint Period**

3 Insys develops and commercializes medical products designed to help patients
 4 address side effects of their disease, treatment or therapy. (Compl., Dkt. No. 1, ¶ 2.) One
 5 of its products—Subsys—is a fentanyl-based medication that rapidly treats intense
 6 episodes of pain that cancer patients often experience and that are not prevented by
 7 routine pain medication (called “breakthrough cancer pain”). (See Compl. ¶ 26.) On
 8 May 2, 2013, almost two years before the Class Period alleged in the Complaint, Insys
 9 filed an amended Registration Statement in connection with its initial public offering of
 10 common stock. ((Ex. 1 (May 8, 2013 Form 8-K); Ex. 2 (May 2, 2013 Registration
 11 Statement)).² The Registration Statement informed investors of the risks that could
 12 adversely affect the Company’s financial performance, including the risks that the
 13 Company’s employees could engage in misconduct or other improper activities and that
 14 the Company could be subject to regulatory actions as a result of infringement of federal
 15 and state laws prohibiting fraud and abuse, kickbacks and the submission of false claims.
 16 (Ex. 2 at 30, 43-44.) In addition, the Company informed investors of the risk that its
 17 financial performance could be affected by undesirable side effects associated with its
 18 products. (Ex. 2 at 38-39.) This information was repeated or reaffirmed in every
 19 subsequent public quarterly and annual report filed by the Company. (Exs. 3-14.)

20 Two months after Insys went public, in July 2013, a *Qui Tam* Complaint asserting
 21 that the Company had violated federal and state False Claims Acts was unsealed. (Ex. 15
 22 (Complaint, *United States ex rel. Furchak v. Insys Therapeutics, Inc. et al.*, 12-cv-2930
 23 (S.D. Tex.)).) The relator, a former sales professional at the Company, alleged that the
 24 Company (i) provided kickbacks to physicians in exchange for prescribing Subsys, (ii)

26 ² All “Ex.” references herein are to the Exhibits to the Declaration of Nicole
 27 Sornsin, which is Exhibit A to Defendants’ Request for Judicial Notice in Support of the
 28 Motion to Dismiss the Class Action Complaint, filed contemporaneously with this
 Motion.

1 promoted off-label usage of Subsys and (iii) improperly encouraged physicians to
2 prescribe Subsys at higher dosages than indicated by the FDA-approved label. (*Id.* ¶¶ 88-
3 113.) The relator alleged that the Company paid medical professionals unreasonably
4 large compensation to give presentations concerning Subsys to other medical
5 professionals and that some physicians were chosen as speakers as a reward for
6 prescribing Subsys. (*Id.* ¶¶ 91-92.) The relator specifically alleged that he personally
7 had witnessed Michael Babich, who was then the Company’s CEO, participate in
8 misconduct. (*Id.* ¶ 101.) After the federal government and the states declined to
9 intervene in the case, the relator voluntarily dismissed the *Qui Tam* Complaint. *United*
10 *States ex rel. Furchak v. Insys Therapeutics, Inc. et al.*, 12-cv-2930, Dkt. Nos. 15 & 16
11 (S.D. Tex.).

12 On December 13, 2013, before the alleged Class Period, the Company filed a
13 Form 8-K and issued a press release to inform investors that it had received a subpoena
14 from the Office of the Inspector General of the Department of Health and Human
15 Services (“HHS”) in connection with an investigation of the Company’s sales and
16 marketing practices for Subsys. (Ex. 16 (Dec. 13, 2013 Form 8-K).)

17 On May 15, 2014 and May 19, 2014, again before the Class Period, two putative
18 class actions were filed against the Company in the District of Arizona; these actions
19 were consolidated and assigned to Judge Snow, and an amended complaint was filed on
20 October 27, 2014. (Ex. 17 (“Prior Securities Complaint”).) The Prior Securities
21 Complaint alleged that throughout a class period running from November 12, 2013 to
22 May 14, 2014, the Company made false and misleading statements indicating that its
23 strong financial performance was attributable to a motivated sales force and the quality of
24 its Subsys product, when in fact the Company’s performance was driven by off-label
25 marketing of Subsys, kickbacks and efforts to persuade doctors to prescribe the
26 medication at higher-than-indicated dosages. (*Id.* ¶¶ 1, 3.)

27 The Prior Securities Complaint substantially repeated the earlier *Qui Tam*
28 Complaint’s allegations about the kickback scheme operated by the Company and

1 Michael Babich's alleged personal involvement in the scheme. (*Id.* ¶¶ 110-131.)
2 According to the Prior Securities Complaint, when concerns about the Company's
3 marketing practices were disclosed to the market, the price of shares of common stock in
4 Insys dropped, causing harm to the putative class members. (*Id.* ¶¶ 26-34.) The first
5 alleged disclosure was a May 8, 2014, Michigan local news report of a criminal
6 complaint charging a Michigan doctor with Medicare fraud in connection with his
7 prescriptions of Subsys. (*Id.* ¶¶ 258-59.) The second alleged disclosure was a May 13,
8 2014, *New York Times* article entitled "Doubts Raised About Off-Label Use of Subsys, a
9 Strong Painkiller", which characterized the Company's marketing practices as aggressive
10 and potentially improper, and which also referenced the then-recent arrest of the
11 Michigan doctor. (*Id.* ¶¶ 275-76.) The Prior Securities Complaint noted that on
12 September 12, 2014, the Company filed a Form 8-K announcing that it had received a
13 subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting
14 documents regarding the Company's sales and marketing practices related to Subsys. (*Id.*
15 ¶ 143.) The consolidated class action litigation based on the Prior Securities Complaint
16 was settled on May 28, 2015, and was finally terminated on December 7, 2015. *Larson*
17 *et al. v. Insys Therapeutics Inc. et al.*, 14-cv-0143, Dkt. Nos. 66 & 80 (D. Ariz.).

18 On August 6, 2015, the Company filed its Form 10-Q reporting financial results
19 for the second quarter of 2015. In that filing, the Company informed investors that a
20 Connecticut-based nurse practitioner, who had participated in the Company's speaker
21 programs, had pleaded guilty to violating the federal Anti-Kickback Statute in connection
22 with payments of approximately \$83,000 from the Company. (Ex. 12 (Aug. 6, 2015
23 Form 10-Q) at 10.) The Company stated that it was investigating the issue. (*Id.*) In the
24 same filing, the Company also informed investors that it had received Civil Investigative
25 Demands from the offices of the Attorneys General of the States of Arizona, Illinois,
26 Massachusetts and Oregon, each seeking documents regarding the Company's sales and
27 marketing practices with respect to Subsys in each State. (*Id.* at 11.) The Company
28 further updated investors on these matters in its Form 10-Q filed on November 5, 2015,

1 which also reported the Company's financial results for the third quarter of 2015. (Ex. 13
2 (Nov. 5, 2015 Form 10-Q) at 11.)

3 **B. The Present Action**

4 On February 2, 2016, Plaintiff filed the Complaint in this case, which alleges that
5 from March 3, 2015 to January 25, 2016 (the "Class Period"), the Company's financial
6 statements and other statements made by Defendants were false and misleading because
7 Defendants failed to inform investors that (i) the Company was engaged in the illegal and
8 improper off-label marketing of Subsys and (ii) certain Insys employees, including
9 Defendant Babich, were involved in an illegal kickback scheme operated for the purpose
10 of increasing prescriptions of Subsys. (Compl. ¶ 40.)

11 **III. ARGUMENT**

12 **A. Legal Standards**

13 1. General Standards Governing Motions to Dismiss

14 Although the Court assumes, for purposes of a motion to dismiss, that all factual
15 allegations in the complaint are true, the Court "need not . . . accept as true allegations
16 that contradict matters properly subject to judicial notice or by exhibit. Nor is the court
17 required to accept as true allegations that are merely conclusory, unwarranted deductions
18 of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979,
19 988 (9th Cir. 2001) (citations omitted).

20 2. Pleading Standards in Securities Fraud Cases

21 To state a claim of securities fraud under Section 10(b) of the Securities Exchange
22 Act of 1934 and SEC Rule 10b-5, Plaintiff must allege: (1) a material misrepresentation
23 or omission of fact; (2) scienter; (3) a connection with the purchase or sale of a security;
24 (4) transaction and loss causation; and (5) economic loss. *See Zucco Partners, LLC v.*
25 *Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009). To state a "control person" claim
26 under Section 20(a), Plaintiff must allege: (1) a primary violation of the securities laws,
27 and (2) that the defendant "exercised actual power or control over the primary violator".
28

1 *Id.*

2 Plaintiff must satisfy the heightened pleading requirements imposed by Federal
3 Rule of Civil Procedure 9(b) as well as the PSLRA. *Rubke v. Capitol Bancorp Ltd.*, 551
4 F.3d 1156, 1164 (9th Cir. 2009). Rule 9(b) requires a complaint to “state with
5 particularity the circumstances constituting fraud”. Similarly, under the PSLRA, the
6 complaint must “specify each statement alleged to have been misleading, the reason or
7 reasons why the statement is misleading, and, if an allegation regarding the statement or
8 omission is made on information and belief, the complaint shall state with particularity all
9 facts on which that belief is formed”. 15 U.S.C. § 78u-4(b)(1) (2012).

10 The PSLRA also requires the complaint to “state with particularity facts giving
11 rise to a ***strong inference*** that the defendant acted with the required state of mind” (*i.e.*,
12 scienter). 15 U.S.C. § 78u-4(b)(2) (emphasis added). “To qualify as ‘strong’ . . . an
13 inference of scienter must be more than merely plausible or reasonable—it must be
14 cogent and at least as compelling as any opposing inference of nonfraudulent intent.”
15 *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). “A court must
16 compare the malicious and innocent inferences cognizable from the facts pled in the
17 complaint, and only allow the complaint to survive a motion to dismiss if the malicious
18 inference is at least as compelling as any opposing innocent inference.” *Zucco Partners*,
19 552 F.3d at 991 (citing *Tellabs*, 551 U.S. at 323).

20 **B. Plaintiff’s Section 10(b) Claim Should Be Dismissed.**

21 Plaintiff’s claim for securities fraud should be dismissed because it fails to plead
22 sufficiently three required elements of a § 10(b) claim: (1) a misrepresentation or
23 omission of a material fact, (2) scienter and (3) loss causation.

24 1. The Complaint Fails to Plead Any Actionable False or Misleading
25 Statements.

26 Plaintiff fails to plead any misstatements with the particularity required or to
27 explain ***why*** any statements were allegedly false or misleading. Furthermore, Plaintiff
28 challenges statements that are “forward-looking” and thus inactionable as a matter of law.

(a) The Complaint Does Not Plead With Particularity Why the Challenged Statements Are False or Misleading.

The Complaint challenges statements in four of the Company’s SEC filings and related press releases (¶¶ 27-39):

- March 3, 2015, Form 10-K (discussing Subsys’ large market share and the Company’s efforts to increase market penetration). (Compl. ¶¶ 27-30.)
- May 11, 2015, Form 10-Q and press release on May 7, 2015 (noting that “Insys had another strong quarter, driven by our twelfth consecutive quarter of Subsys sales growth. We expect this will remain our largest near-term revenue driver as we advance the many projects in our pipeline through clinical trials and bring them to market.” Also noting that “[b]y continuing to focus our clinical, regulatory and commercial expertise on developing and successfully commercializing innovative products, we expect to deliver long-term value for our shareholders”). (Compl. ¶¶ 33-34.)
- August 6, 2015, Form 10-Q and press release (containing substantially similar language as the May 11, 2015 Form 10-Q and noting that “we are pleased to have submitted the NDA for Dronabinol Oral Solution”). (Compl. ¶¶ 35-36.)
- November 5, 2015, Form 10-Q and press release (containing substantially similar language as the May 2015 and August 2015 reports). (Compl. ¶¶ 37-39.)

The Complaint alleges that these statements were false and misleading because the “Defendants failed to disclose that: (i) the Company was engaged in the illegal and improper off-label marketing of Subsys; [and] (ii) certain Insys employees—including Defendant Babich—were complicit in an illegal kickback scheme operated for the purpose of increasing prescriptions of Subsys”. (Compl. ¶ 40.)

Plaintiff fails to plead with particularity what, precisely, was false or misleading about each of these particular statements and why these statements were false or misleading when they were made. *See* 15 U.S.C. § 78u-4(b)(1) (requiring the Plaintiff to allege with particularity “the reason or reasons why the statement is misleading”). “A litany of alleged false statements, unaccompanied by the pleading of specific facts indicating *why* those statements were false, does not meet this standard.” *Metzler Inv.*,

1 540 F.3d at 1070 (emphasis added). Notably, the Complaint does not allege that any of
2 the financial results and other historical facts reported in these statements (*e.g.*, the
3 Subsys market share, revenues, historical sales growth or profitability) were inaccurate.
4 Rather, the Complaint alleges that the Defendants' statements were misleading by
5 implying that the Company's business and operations complied with relevant regulations.
6 Such allegations alone, however, are insufficient as a matter of law. *See id.* at 1071
7 (rejecting the allegation that a company's financial statements were false "because they
8 created the overarching impression that the Company was outperforming expectations
9 and continually increasing revenue through legitimate business means").

10 Moreover, the Company informed investors, in each of its public SEC filings since
11 it went public, of the significant risks associated with employee misconduct in marketing
12 and sales practices and other activity in the highly regulated industry in which the
13 Company operates. (Ex. 2 at 30, 38-39 & 43-44; Ex. 3 at 38, 44-45 & 48; Ex. 4 at 27;
14 Ex. 5 at 25; Ex. 6 at 41 & 46-48; Ex. 7 at 27; Ex. 8 at 29; Ex. 9 at 29; Ex. 10 at 22, 39, &
15 43-46; Ex. 11 at 29; Ex. 12 at 29-30; Ex. 13 at 29; Ex. 14 at 36, 40-42.) The Company
16 addressed these risks in each of its public filings beginning *before the Class Period* from
17 the time the Company went public. (Exs. 2-9.) In addition, the Company informed
18 investors of actual government investigations into the exact employee misconduct about
19 which the Company had warned investors since going public in 2013. (Ex. 8 at 12; Ex. 9
20 at 10-11; Ex. 10 at 84-85; Ex. 11 at 11-12; Ex. 12 at 10-11; Ex. 13 at 10-11; Ex. 14 at 85-
21 86; Ex. 16 & Ex. 35.) When viewed in the context of those contemporaneous and
22 repeated disclosures, there is no reasonable inference that the challenged statements were
23 misleading by omission. *See In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1414 (9th
24 Cir. 1994) (citing the "unremarkable proposition that statements must be analyzed in
25 context"); *see also Sprewell*, 266 F.3d at 988 (holding that a court need not accept an
26 allegation that is contradicted by documents of which the court may take judicial notice).
27 Accordingly, Plaintiff has failed to plead falsity with sufficient particularity.
28

(b) Forward-Looking Statements Are Protected by the Statutory Safe Harbor.

Many of the statements challenged by Plaintiff are “forward-looking statements” that cannot form the basis of a claim under the securities laws. The PSLRA provides a “safe harbor” for “forward-looking statements”, which are defined to include: “(A) a statement containing a projection of revenues, income . . . or other financial items; (B) a statement of the plans and objectives of management for future operations . . . ; (C) a statement of future economic performance . . . ; [and] (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C)”. 15 U.S.C. § 78u-5(i)(1). Defendants “shall not be liable” for any forward-looking statements if: the statement is “identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement” *or* plaintiffs do not adequately plead that the statement was made “with actual knowledge” that the statement was false or misleading. 15 U.S.C. § 78u-5(c)(1); *see In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111-13 (9th Cir. 2010).

The Complaint challenges the following forward-looking statements:

- “Through our ongoing commercial initiatives, we believe we can continue to grow our market share and net revenue for Subsys.” (Compl. ¶ 28.)
- “We believe that we can continue to increase Subsys net product revenue . . .” (*Id.* ¶ 29.)
- “We expect [Subsys] will remain our largest near-term revenue driver as we advance the many projects in our pipeline through clinical trials and bring them to market.” (*Id.* ¶¶ 33, 35.)
- “[W]e expect to deliver long-term value for our shareholders.” (*Id.*)
- “We . . . see opportunity for further market share gains in the coming quarters.” (*Id.* ¶ 38.)

These are classic forward-looking statements because, when “examined as a whole, the challenged statements related to future expectations and performance”. *Police*

1 *Retirement Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1059 (9th
2 Cir. 2014).

3 Each of these forward-looking statements is in the “safe harbor” because it was
4 identified as a forward-looking statement and accompanied by meaningful cautionary
5 statements. In every SEC filing made during the Class Period and on every press release
6 or earnings announcement cited in the Complaint, Insys advised investors that its report
7 or announcement contained forward-looking statements relating to the Company’s future
8 prospects. For example, in the 2014 Annual Report, Insys warned investors:

9 The information in this Annual Report on Form 10K, or this
10 Form 10K . . . contains forward-looking statements and
11 information . . . In evaluating these statements, you should
12 specifically consider various factors, uncertainties and risks
13 that could affect our future results or operations as described
14 from time to time in our SEC reports, including those risks
15 outlined under the heading “Risk Factors” in Item 1A of this
16 Form 10K.

17 (Ex. 10 at 57.) The Company repeated similar warnings in subsequent SEC filings
18 throughout the Class Period. (*See* Exs. 11-13.) The Company also provided cautions in
19 each relevant press release issued by the Company, including those now challenged by
20 Plaintiff. (Exs. 18-29.) These warnings and cautions are similar to the warnings the
21 Ninth Circuit has repeatedly found adequate to put statements within the safe harbor. *See*
22 *Police Retirement Sys.*, 759 F.3d at 1059 (“I would like to inform you that comments
23 mentioned on today’s call may be deemed to contain forward-looking statements. Actual
24 results may differ materially from those expressed or implied, as a result of certain risks
25 and uncertainties. These risks and uncertainties are described in detail in the company’s
26 SEC filings.”); *In re Cutera*, 610 F.3d at 1112.

27 In addition, the Company informed investors in its SEC filings that there were
28 “important factors that could cause actual results to differ materially from those in the
forward-looking statement.” 15 U.S.C. § 78u-5(c)(1)(A); *see Police Retirement Sys.*, 759
F.3d at 1058. In particular, the Company expressly warned investors of the same

1 regulatory and compliance risks Plaintiff now erroneously contends were concealed. For
 2 example, the 2014 Annual Report warns:

- 3 • “[O]ur ability to continue to generate revenues from these products
 4 will depend on a number of factors, including, but not limited to . . .
 5 our ability to comply with regulatory requirements.” (Ex. 10 at 22.)
- 6 • “Our employees may engage in misconduct or other improper
 7 activities, including noncompliance with regulatory standards . . .
 8 We are exposed to the risk of fraud or other misconduct.” (*Id.*
 9 at 39.)
- 10 • “In particular, sales, marketing and business arrangements in the
 11 healthcare industry are subject to extensive laws and regulations
 12 intended to prevent fraud, misconduct, kickbacks, self dealing and
 13 other abusive practices. These laws and regulations may restrict or
 14 prohibit a wide range of pricing, false claims, discounting, marketing
 and promotion, sales commission, customer incentive programs and
 other business arrangements. [M]isconduct could also involve . . .
 illegal promotion of a drug product for off label use, which could
 result in regulatory sanctions and serious harm to our reputation.”
 (*Id.*)

15 These risk factors were repeated or reaffirmed in the Company’s subsequent SEC filings
 16 throughout the Class Period. (Exs. 11-13.)

17 When forward-looking statements are accompanied by such cautionary statements,
 18 the statements cannot be used as the basis of a securities law claim and “the state of mind
 19 of the individual making the statement is irrelevant”. *In re Cutera*, 610 F.3d at 1112.
 20 Even if this Court were to conclude that these cautions were inadequate, however, the
 21 Complaint must allege “facts that would create a strong inference that the defendants
 22 made the forecast(s) at issue with actual knowledge that the statement was false or
 23 misleading”. *Id.* (citing 15 U.S.C. § 78u-5(c)(1)(B)(i)). As set forth below, Plaintiff fails
 24 to allege facts showing any degree of scienter, much less actual knowledge on the part of
 25 any Defendant who made forward-looking statements. The forward-looking statements
 26 challenged in the Complaint are not actionable.

2. The Complaint Fails to Plead Facts Giving Rise to a “Strong Inference” of Scienter.

Even if the Complaint had pleaded an actionable misstatement, it does not “state with particularity facts giving rise to a strong inference” that any Defendant made a misstatement “intentionally or with deliberate recklessness”. 15 U.S.C. § 78u-4(b)(2)(A); *Oregon Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 607 (9th Cir. 2014). In fact, the Complaint contains a single, boilerplate allegation of scienter:

Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing Defendants participated in a scheme to defraud and committed acts that operated as a fraud or deceit on purchasers of the Company’s common stock during the Class Period.

(Compl. ¶ 58.) This allegation consists of unsupported conclusions, and thus does not create any strong inference of scienter on the part of any Defendant. *See Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 743 (9th Cir. 2008); *see also Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 (9th Cir. 2002) (“[P]laintiffs who plead the required state of mind in general terms of mere ‘motive and opportunity’ or ‘recklessness’ fail to meet the PSLRA’s heightened pleading requirements”); *Common’s Workers of Am. Plan for Emps.’ Pensions & Death Benefits v. CSK Auto Corp.*, 2007 WL 951968, at *4 (D. Ariz. Mar. 28, 2007) (finding general allegations about defendants’ positions and access to non-public material information insufficient to establish that defendants acted deliberately or recklessly).³ Accordingly, Plaintiff has failed to

³ The only factual allegation in the Complaint potentially related to any Defendant’s state of mind is the allegation that Defendant Kapoor stated that Defendant Babich resigned on November 2, 2015, because Babich “was closest to the issues that federal prosecutors were looking at”. (Compl. ¶ 47, p. 12.) There is only one alleged misstatement occurring after those events: Insys’s third-quarter 2015 results and an accompanying statement by Defendant Kapoor that “We have driven top line revenue expansion with our market-leading brand, Subsys, and see opportunity for further market share gains in the coming quarters.” (Compl. ¶ 38.) The Complaint does nothing to allege that these statements were false or misleading in light of Kapoor’s alleged knowledge concerning Babich. Accordingly, that allegation therefore does not create any inference of scienter, much less a strong one.

1 sufficiently plead scienter.

2 3. The Complaint Fails to Plead Loss Causation.

3 The Complaint also fails to plead another essential element of a securities fraud
4 claim: loss causation. In *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005),
5 the Supreme Court made clear that Plaintiff must plead a causal link between the
6 misrepresentations and actual economic loss by alleging that the revelation of the
7 misrepresentation caused the price of the security to decrease. *See id.* at 342-46.
8 Accordingly, Plaintiff must “allege specific statements . . . that were made untrue or
9 called into question by subsequent public disclosures”. *Oregon Public Emps. Ret. Fund*,
10 774 F.3d at 608.

11 The Complaint identifies five specific news articles (so-called “Corrective
12 Disclosures”) that Plaintiff claims revealed the “truth” concealed by the alleged
13 misstatements and were allegedly followed by decreases in the market price of the
14 Company’s securities:

- 15 • An April 24, 2015, article published by the Southern Investigative
16 Reporting Foundation (“SIRF”) entitled “Insys Therapeutics and the New
17 ‘Killing It’”, which addressed a purportedly large number of “adverse
18 events”, including death, suffered by patients using Subsys, and described
the allegations in the *Qui Tam* Complaint. (Compl. ¶¶ 41-42.) (Ex. 30.)
- 19 • A May 20, 2015, article published by Seeking Alpha entitled “Top
20 prescribers of Insys Therapeutics’ Subsys arrested on drug charges”
reporting that two Alabama-based physicians, prescribers of Subsys, had
21 been arrested on healthcare fraud charges. (*Id.* ¶¶ 43-44.) (Ex. 31.)
- 22 • A June 25, 2015, article published by *The New York Times* entitled “Nurse
23 Pleads Guilty to Taking Kickbacks from Drug Maker”, which reported on
the Connecticut nurse practitioner, described above, pleading guilty to
24 receiving illegal payments in exchange for writing Subsys prescriptions.
(*Id.* ¶¶ 45-46.) (Ex. 32.)
- 25 • A December 3, 2015, article published by SIRF entitled “Murder
26 Incorporated: Insys Therapeutics, Part I”, alleging that Michael Babich had
27 been forced to resign by John Kapoor, the Company’s chairman, and that
the Company was operating an illegal kickback scheme to promote off-
28 label marketing of Subsys. (*Id.* ¶¶ 47-48.) (Ex. 33.)

- A January 25, 2016, article published by SIRF entitled “The Brotherhood of Thieves: Insys Therapeutics”, which alleged that the Company was continuing to engage in improper off-label marketing of Subsys. (*Id.* ¶¶ 49-50.) (Ex. 34.)

In fact, however, many of these so-called Corrective Disclosures identified by Plaintiff simply repeated allegations that were contained in the *Qui Tam* Complaint or in the Prior Securities Complaint and thus were not new news. For example, Plaintiff’s first supposed Corrective Disclosure, an article published by SIRF on April 24, 2015, extensively quotes or paraphrases allegations contained in both Complaints, including allegations concerning kickbacks, off-label marketing of Subsys and efforts to persuade physicians to prescribe a higher-than-indicated dose. (Ex. 30.) The Prior Securities Complaint, which was filed in 2014, had been public long before the Class Period. Indeed, the Company described the allegations in the underlying litigations in its August 12, 2014, Form 10-Q and in subsequent SEC filings. (Exs. 8-14.)⁴ The Prior Securities Complaint, in turn, repeated many of the allegations from the earlier *Qui Tam* Complaint that had become public in July 2013, again well before the beginning of the Class Period. In particular, the allegation that Defendant Babich was involved in improper conduct had already been made in both of the prior Complaints. (Ex. 15 ¶ 101; Ex. 17 ¶ 111.)

As another example, Plaintiff’s fourth Corrective Disclosure, a SIRF article published on December 3, 2015, describes allegations that the Company’s “prior authorization unit” provided false information to pharmacy benefit managers so that they would cover Subsys, and those allegations are repeated in Plaintiff’s fifth Corrective Disclosure, a SIRF article published on January 25, 2016. (Exs. 33, 34.) But those allegations were also recycled from the Prior Securities Complaint, which even refers to a confidential witness who allegedly worked in the “prior authorization unit” and witnessed

⁴ The first Corrective Disclosure also refers to instances of adverse events associated with Subsys being reported to the FDA. The Company had warned investors on several occasions, both prior to and during the Class Period, of the risk that patients taking Subsys might suffer side effects. (*See, e.g.*, Ex. 6 (March 5, 2014 Form 10-K) at 48; Ex. 10 (March 3, 2015 Form 10-K) at 45-46.) In addition, the information contained in the article concerning potential adverse effects did not make untrue or call into question any of the prior alleged misstatements.

1 improper conduct. (Ex. 17 ¶¶ 84, 85.)

2 In addition, many of Plaintiff's Corrective Disclosures refer to governmental
3 investigations of Insys or its employees that were not new. For example, the first
4 Corrective Disclosure referred to investigations initiated by HHS and a "grand jury that
5 has been empaneled in Boston". (Ex. 30.) The second Corrective Disclosure, a May 20,
6 2015 Seeking Alpha article, stated that "[i]n September, the Massachusetts Attorney
7 General issued a subpoena requesting documents pertaining to its commercial practices
8 supporting Subsys." (Ex. 31.) (Although the article refers to a subpoena from the
9 "Massachusetts Attorney General", it is presumably referring to the subpoena from the
10 United States Attorney for the District of Massachusetts issued September 8, 2014.)
11 However, the Company previously had informed investors about the Massachusetts U.S.
12 Attorney's investigation on September 12, 2014, before the Class Period (Ex. 35
13 (Sept. 12, 2014 Form 8-K)), and previously had informed investors about the HHS
14 investigation on December 13, 2013, nearly 17 months prior to the article's publication
15 and well before the Class Period. (Ex. 16 (Dec. 13, 2013 Form 8-K).) In fact, Plaintiff's
16 second Corrective Disclosure noted that "Insys has been under scrutiny for some time for
17 its Subsys marketing practices". (Ex. 31.) The existence of those investigations was not
18 new news.⁵ Further, for the same reasons discussed above in Part III.B.1, Plaintiff fails to
19 plead how the governmental investigations revealed that Defendants' descriptions of the
20 Company's financial situation were false or misleading. *See Metzler Inv.*, 540 F.3d
21 at 1071.

22 Other information reported in the Corrective Disclosures concerned
23 contemporaneous events that the Company could not have previously disclosed, and
24 which did not reveal that any of the Defendants' prior alleged misstatements were false or

25
26 ⁵ In discussing the Seeking Alpha article, the Complaint (¶ 43) focuses on the
27 indictment of two physicians who wrote prescriptions for Subsys. According to the
28 article, the indictment alleged that the physicians dispensed controlled substances
"outside professional practice and not for legitimate medical purpose". (Ex. 31.) But
there are no allegations of misconduct by Insys in the article's description of the
indictment.

misleading. Plaintiff's third Corrective Disclosure, a June 25, 2015, article published by *The New York Times*, reported that Connecticut nurse-practitioner Heather Alfonso (who was not an Insys employee) pleaded guilty to charges of violating the federal Anti-Kickback Statute. (Ex. 32.) In its next Form 10-Q, the Company disclosed this guilty plea as a development in the ongoing federal investigations.⁶ (Ex. 12 (Aug. 6, 2015 Form 10-Q) at 10.) Similarly, Plaintiff's fourth Corrective Disclosure, an article published December 3, 2015, asserted that "Defendant Babich had been forced to resign from the Company". (Compl. ¶ 47.) However, Defendant Babich's resignation had just occurred, and the Company promptly informed investors of it. (Ex. 13 (Nov. 5, 2015 Form 10-Q) at 30.)

Because none of the Corrective Disclosures alleged by Plaintiff contained new news that revealed that the alleged misstatements were false or misleading, Plaintiff has failed to plead loss causation.

C. Plaintiff's Section 20(a) Claim Must Be Dismissed.

Because Plaintiff fails to state a claim for violation of § 10(b), Plaintiff's claim under § 20(a) necessarily fails as well. Section 20(a) provides for joint and several liability for "[e]very person who, directly or indirectly, controls any person liable under" the securities laws or SEC rules thereunder. 15 U.S.C. § 78t(a). To state a claim of "control person liability" under § 20(a), therefore, Plaintiff must allege: (1) "a primary violation of federal securities law" and (2) that "the defendant exercised actual power or control over the primary violator". *Zucco Partners, LLC*, 552 F.3d at 990. As explained above, Plaintiff has failed in several respects to allege a primary violation of § 10(b) and Rule 10b-5; thus, the § 20(a) claim fails on the first prong. *See, e.g., Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1206 n.2 (9th Cir. Feb. 1, 2016) (explaining that liability under § 20(a) "rises or falls with the primary violation claim").

⁶ The Company disclosed this guilty plea once again in its subsequent (and most recent) Form 10-Q, along with a description of remedial measures the Company had taken after a review by its board's Compliance Committee and outside counsel. (Ex. 13 (Nov. 5, 2015 Form 10-Q) at 11; *see also* Ex. 14 (Feb. 29, 2016 Form 10-K) at 85.)

1 **IV. CONCLUSION**

2 For all the foregoing reasons, the Complaint should be dismissed.

3 DATED: March 15, 2016

4
5 SNELL & WILMER L.L.P.

6 s/Nicole E. Sornsin

7 Don Bivens

Nicole E. Sornsin

8 One Arizona Center

9 400 E. Van Buren

Phoenix, AZ 85004-2202

10 CRAVATH, SWAINE & MOORE LLP

11 Daniel Slifkin

12 David M. Stuart

Worldwide Plaza

13 825 Eighth Avenue

14 New York, NY 10019

15 *Attorneys for Defendants*

CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2016, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following CM/ECF registrants:

Francis J. Balint, Jr.
Andrew S. Friedman
BONNETT FAIRBOURN FRIEDMAN & BALINT, P.C.
2325 E. Camelback Road, Suite 300
Phoenix, Arizona 85016
Attorneys for Plaintiff

s/Jennifer Thomes
23686781